K101740

SECTION 5: 510(K) Summary

SEP 20 2010

Submitter:	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803
Contact Person:	Vic Zhang Regulatory Affairs Specialist Phone: 781-221-2266 x162 Fax: 781-425-5049 Email: xzhang@lemaitre.com
Date Prepared:	June 18, 2010
Trade Name:	AlboSure™ Cardiovascular Patch
Common Name:	Cardiovascular Patch
Classification Name:	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Predicate Device:	Hemashield Finesse Knitted Cardiovascular Patch (K962342)
Device Description:	AlboSure Polyester Vascular Patch is a knitted polyester fabric, impregnated with bovine collagen and contains glycerol as softening agent.
Intended Use:	The AlboSure Polyester Vascular Patch is indicated for cardiac and vascular patch grafting.
Summary of Technological Characteristics:	AlboSure Polyester Vascular Patch is a knitted polyester fabric, impregnated with bovine collagen and contains glycerol as softening agent.
Summary of Product Testing:	Following tests have been performed: Tensile Strength, Burst Strength, Wall Thickness, Suture Retention Strength, Water Permeability.
Summary of Pre-clinical Study:	The biocompatibility of the device was tested per ISO10993-1.
Conclusion:	LeMaitre Vascular has demonstrated that the AlboSure Polyester Vascular Patch is substantially equivalent to the predicate device based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LeMaitre Vascular, Inc.
c/o Mr. Vic Zhang
Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

SEP 2 0 2010

Re: K101740
Trade/Device Name: AlboSure™ Polyester Vascular Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: Class II
Product Code: DXZ
Dated: June 18, 2010
Received: June 21, 2010

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATION FOR USE STATEMENT

510(k) Number (if known): K101740

Device Name: AlboSure™ Polyester Vascular Patch

SEP 20 2010

Indications for Use:

The AlboSure Polyester Vascular Patch is indicated for cardiac and vascular patch grafting. The fabric is recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

Prescription Use____X____ and/or Over-The Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE ID NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovasculo
510(k) Number K101740